12. (Amended) The drug product of Claim 1, wherein said drug comprises fluticasone propionate or a solvate thereof.

13. (Amended) The drug product of Claim 1, wherein said drug comprises beclomethasone dipropionate or a solvate thereof.

14. (Amended) The drug product of Claim 1, wherein said drug comprises a salt, ester or solvate of salmeterol.

15. (Amended) The drug product of Claim 1, wherein said drug comprises a combination of a salt, ester or solvate of salmeterol and a salt, ester or solvate of ipratropium.

16. (Amended) The drug product of Claim 1, wherein said drug comprises a combination of fluticasone propionate or a solvate thereof and a salt, ester or solvate of salmeterol.

Please delete Claim 11 without prejudice or disclaimer thereto.

II. REMARKS

A. Introduction

Applicants submit this Response in a bona fide attempt to (i) advance the prosecution of this case, (ii) answer each and every ground of objection and rejection as set forth by the Examiner, (iii) place the claims in a condition for allowance, and (iv) place the case in better condition for consideration on appeal. Applicants respectfully request reexamination and reconsideration of the above referenced patent application in view of this Response.

As indicated above, Applicants have amended Claims 1-10 and 12-16. Claim 11 has also been deleted without prejudice or disclaimer thereto.

Attached hereto is a marked-up version of the changes made to the claims by the current amendments. The attached page is captioned "**Version With Markings To Show Changes Made.**"

Applicants respectfully submit that the noted amendments merely make explicit that which was (and is) disclosed or implicit in the original disclosure. The amendments thus add nothing that would not be reasonably apparent to a person of ordinary skill in the art to which the invention pertains.

B. Response to Rejections

The Examiner has rejected Claims 1, 2, 5, 6, 10 and 11 under 35 U.S.C. § 103(a) as being unpatentable over Alband (5,775,321) in view of Cullen (3,371,825). The Examiner contends:

> The reference of Alband substantially discloses an inhalation device that includes an HFA propellant combined with an ethanol and a medicament/drug product.
>
> The reference of Cullen, at column 1, lines 24-34, column 1, lines 45-55, and col. 2, lines 3-5, suggests that when a hydrocarbon propellant for packaged medicaments/drugs is combined with an inadvertent water content, as which is present with alcohols, an undesirable acid such as hydrofluoric acid is formed, and a breakdown of the propellant occurs. The reference of Cullen further suggests that a moisture absorbing material placed with the propellant of an aerosol medical discharge device would be desirable in order to prevent this propellant breakdown. One example of an absorbent/desiccant that can be used is silica gel.
>
> Accordingly, it would have been obvious in view of Cullen to have provided a moisture absorbent with the propellant of the device of Alband in order to prevent propellant breakdown.

The Examiner has also rejected Claims 7-9 under 35 U.S.C. § 103 as being unpatentable over Alband and Cullen as applied to Claim 6, and further in view of Shichman et al. (5,322,161,). The Examiner contends:

> The reference of Shichman et al. at column 2, lines 21-34, suggests that is common practice to contain a packaged absorbent (e.g., silica gel) in its own nylon mesh pouch when an absorbent is packaged with content where it is desired to reduce moisture contamination of the packaged product. Apparently, this would prevent uncontrolled movement of the absorbent per se in the package with respect to the packaged product. The pouch taught... may either be loose or attached directly to the package structure. Accordingly, it would have been obvious in view of Shichman et al. to have provided the absorbent material of Cullen, as applied above to the delivery device of Alband, in a nylon mesh bag (for the absorbent) for the purpose of preventing uncontrolled movement of the absorbent material with respect to the propellant and drug of Alband, wherein the pouch is loose or attached to the delivery apparatus.

The Examiner further contends:

> [T]he drug products claimed in Claims 3 and 12-16, and their intended effect as medication for the human body, are known and are prior art.
>
> To have used the absorbent and inhaler combination obvious from Alband and Cullen, as indicated above, for any particular known medicament/drug, such as those recited in Applicant's Claims 3 and 12-16, would have further been obvious in order to provide metered drug delivery of such a drug to the human body.

Contrary to the Examiner's contentions, Applicants respectfully submit that Claims 1-10 and 12-16, as amended, define an invention that is unobvious over the cited references, alone or in combination.

In determining what is and what is not obvious under § 103, all properties and advantages not in the prior art must be considered. See *In re Wright*, 848 F.2d 1216, 6 U.S.P.Q. 2d 1959, 1962 (Fed. Cir. 1988) ("Factors including unexpected results, new features, solution of a different problem, novel properties, are all considerations in the determination of obviousness in terms of 35 U.S.C. § 103"). Indeed, it is the invention as a whole, including distinct functions that must be considered in obviousness determinations.

Further, obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. See *ACS Hospital Systems, Inc. v. Monteflore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 922 (Fed. Cir. 1984).

As indicated above, independent Claim 1 has been amended to reflect that the drug product includes a flexible package that is adapted to sealably receive the pressurized container. Claim 1, as amended, further provides that the moisture absorbing material is disposed within the flexible package.

Applicants respectfully submit that the claimed drug product is not taught or suggested by the cited references. Indeed, as noted by the Examiner, Cullen merely suggests that a moisture absorbing material placed "with the propellant" of an aerosol discharge device would be desirable in order to prevent [the] propellant breakdown. Alband merely discloses an aerosol discharge device having a propellant.

Applicants accordingly submit that independent Claim 1 and, hence, Claims 2-10 and 12-16 dependent thereon, are not obvious in view of the art of record and should be deemed allowable.

Applicants have also reviewed the prior art made of record and not relied upon by the Examiner and has found them not to teach or make obvious the present invention.

III. CONCLUSION

Applicants having answered each and every ground of objection and rejection as set forth by the Examiner, and having added no new matter, believe that this response clearly overcomes the references of record, and now submit that all claims in the above-referenced patent application are in condition for allowance and the same is respectfully solicited.

If the Examiner has any further questions or comments, Applicants invite the Examiner to contact the Attorneys of Record to expedite prosecution of the application.

Respectfully submitted,
GlaxoSmithKline

By _____
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Dated: 10/22/2002

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Dan Younan
Name of person mailing document

Dan Younan

VERSION WITH MARKINGS TO SHOW CHANGES

In the claims:

Claim 11 has been deleted without prejudice or disclaimer thereto.

Claims 1-10 and 12-16 have been amended as follows:

1. (Twice Amended) A drug product, comprising:

a drug formulation comprising a mixture of a least a drug and **[an]** a HFA propellant;

a pressurized container filled with said drug formulation; **[and]**

a flexible package being adapted to sealably receive said pressurized container; and

a moisture absorbing material **[located]** **disposed** within **[the pressurized container]** **said flexible package**.

2. (Twice Amended) The drug product of **[claim 1]** **Claim 1,** wherein **[the]** **said** pressurized container is a component of a metered dose inhaler.

3. (Twice Amended) The drug product of **[claim 1]** **Claim 1,** wherein **[the]** **said** drug **[is]** **comprises** albuterol sulfate.

4. (Twice Amended) The drug product of **[claim 3]** **Claim 3,** wherein **[the]** **said** HFA propellant **[is]** **comprises HFA-**134a.

5. (Twice Amended) The drug product of **[claim 2]** **Claim 2,** wherein **[the]** **said** moisture absorbing material **[is]** **comprises** a desiccant.

6. (Twice Amended) The drug product of **[claim 5]** **Claim 5,** wherein **[the]** **said** desiccant **[is]** **comprises** a material selected from the group consisting of nylon, silica gel, zeolite, alumina, bauxite, anhydrous calcium sulphate, activated bentonite clay, water absorbing clay, molecular sieve and contributions thereof.

7. (Twice Amended) The drug product of **[claim 6]** **Claim 6,** wherein **[the]** **said** desiccant is **[contained within]** **disposed in** a **nylon mesh** sachet **[constructed from a nylon mesh]**.

8. (Twice Amended) The drug product of **[claim 7]** **Claim 7,** wherein **[the]** **said nylon mesh** sachet is loose within **[the pressurized container]** **said flexible package**.

9. (Twice Amended) The drug product of **[claim 7]** **Claim 7,** wherein **[the]** **said nylon mesh** sachet is fixedly attached to **[the pressurized container]** **said flexible package**.

10. (Twice Amended) The drug product of **[claim 6]** **Claim 6,** wherein **[the]** **said** desiccant is in the form of granules or beads suitably large in size to avoid clogging a valve in **[the]** **said** metered dose inhaler.

12. (Amended) The drug product of **[claim 1]** **Claim 1,** wherein **[the]** **said** drug **[is]** **comprises** fluticasone propionate or a solvate thereof.

13. (Amended) The drug product of **[claim 1]** **Claim 1,** wherein **[the]** **said** drug **[is]** **comprises** beclomethasone dipropionate or a solvate thereof.

14. (Amended) The drug product of **[claim 1]** **Claim 1,** wherein **[the]** **said** drug **[is]** **comprises** a salt, ester or solvate of salmeterol.

15. (Amended) The drug product of **[claim 1]** **Claim 1,** wherein **[the]** **said** drug **[is]** **comprises** a combination of a salt, ester or solvate of salmeterol and a salt, ester or solvate of ipratropium.

16. (Amended) The drug product of **[claim 1]** **Claim 1,** wherein **[the]** **said** drug **[is]** **comprises** a combination of fluticasone propionate or a solvate thereof and a salt, ester or solvate of salmeterol.